1. What is an externally administered IBC?

An externally administered IBC is an IBC that is administered by an entity (i.e. institution, commercial entity, university, etc.) other than the institution performing research subject to the National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines).

Back to Top

2. Can an institution that does not have an IBC use an externally administered IBC to review and approve research subject to the NIH Guidelines?

Yes, an institution may use an externally administered IBC provided certain conditions are met.

Back to Top

3. What are the conditions under which an institution may use an externally administered IBC?

The IBC must be registered with the National Institutes of Health (NIH) Office of Science Policy (OSP) by the institution that is conducting research subject to the *NIH Guidelines* (not by the entity administering the IBC).

The expertise and membership of the externally administered IBC must be appropriate for the registering institution and in keeping with research conducted at that institution, include plant or animal experts, a biological safety officer, or other expertise as appropriate. The IBC must also include at least two unaffiliated members who can represent the interests of the community surrounding the registering institution. If the entity administering the IBC and the registering institution are geographically distant, it will be important to ensure that the unaffiliated members are local to the registering institution (where the research is taking place).

The IBC must also provide documentation to NIH OSP that (1) the IBC has knowledge of local institutional characteristics – such as investigator training, laboratory conditions, and operating procedures, and (2) an individual at the registering institution has the authority and responsibility to implement the IBC's directives. A single individual can help fulfill both requirements (such as a biosafety officer or laboratory director).

Back to Top

4. How do I register an externally administered IBC with NIH OSP?

NIH OSP encourages entities to register and update IBC documentation via the Institutional Biosafety Committee Registration Management System (IBC-RMS). IBC-RMS is a Web-based registration management system that supports the online submission of IBC registrations and annual registration updates. More information on IBC-RMS can be found at: http://ibc-rms.od.nih.gov/ However, registrations will still be accepted through mail, fax, or email.

If an entity chooses not to utilize the IBC-RMS, then the following information should be mailed, faxed, or emailed to NIH OSP.

- A complete roster listing all members of the IBC; your roster should contain complete contact information for each person, including:
- Name
- Title
- Business mailing address
- Phone number
- Fax number
- Email
- The role of each member, g., chairperson, contact person, non-institutional members, special experts as relevant, etc.
- Biosketches (e.g., curricula vitae, résumé) for every member on the committee
- Documentation signed by an official at both the institution establishing the IBC and the organization externally administering the The documentation should indicate that the institution that administers the IBC has agreed to be the IBC of record for the establishing institution and thus will fully comply with the requirements set forth in the *NIH Guidelines*. Also, the documentation should include a statement that the establishing institution is accepting the authority of the externally administered IBC.

Listed below are various options for submitting information on your committee to NIH OSP:

Mail:

Michelle Johnson-Lancaster
IBC Coordinator
National Institutes of Health

Office of Science Policy

6705 Rockledge Dr., Suite 750Bethesda, MD 20892-7985

(Non-USPS, FedEx, UPS, etc.):

Michelle Johnson-Lancaster
IBC Coordinator

National Institutes of Health
Office of Science Policy
6705 Rockledge Dr., Suite 750
Bethesda, MD 20817-1814

Fax: (301) 496-9839
ATTN: Michelle Johnson-Lancaster

Email:
JohnsoM1@od.nih.gov

Back to Top

5. Can a multi-site clinical trial use the same externally administered IBC to review and approve the trial at each trial site?

Yes, provided that each individual trial site registers the IBC with NIH OSP and the IBC fulfills the necessary membership and expertise requirements. This includes the requirement External IBCs FAQ/April 2015 that the IBC have at least two unaffiliated members to represent the interests of the local community at each trial site.

Back to Top

6. How do I contact NIH OSP for more information?

Questions regarding the registration of an externally administered IBC may be directed to NIH OSP staff at NIHguidelines@od.nih.gov. Staff may also be reached at (301) 496-9838.

Back to Top